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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,024

10/03/2005

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EXAMINER

CHUNG, SUSANNAH LEE

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

07/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,024	CHAKRAVARTY ET AL.	
	Examiner	Art Unit	
	SUSANNAH CHUNG	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 4-19, 29 and 32-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 20-28, 30 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/6/06 and 11/23/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-44 are pending in the instant application.

Priority

This application is a 371 of PCT/US04/09713, filed 03/30/2004, which claims benefit of 60/460,106, filed 04/03/2003.

Information Disclosure Statement

The information disclosure statement (IDS), filed on 3/6/06 and 11/23/07 have been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Response to Election/Restrictions

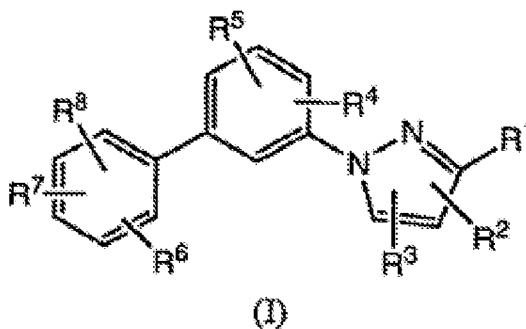
Applicant's election with traverse of Group I in the reply filed on 6/13/2007 is acknowledged. Applicants traverse stating that the technical feature of the instant claims is "a pyrazole substituted with a substituted biphenyl." (See Response page 2, lines 4-5.) This is acknowledged, but Examiner respectfully disagrees. Claim 1 claims four compounds of formula (I)-(IV), which have different cores. Some contain a pyrazole substituted with a biphenyl and others contain a pyrazole substituted with a heterocyclic ring. The compounds of formula (I)-(IV) result in very different compounds which do not share the same core. In addition, the invention of Group II requires different search parameters that are not required to search the compounds of Group I, i.e. additional databases such as pubmed. Applicants have elected example 67 for initial search and examination. Example 67 contains a pyrazole substituted with a biphenyl core of formula (I). This core will be search.

Therefore, for the above reasons, the requirement is still deemed proper and is therefore maintained.

Scope of the Elected Invention

Claims 1-44 are pending in this application. Claims 4-19, 29, and 32-44 are withdrawn from further consideration by the examiner, 37 C.F.R. §1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

The scope of the elected subject matter that will be examined and searched is as follows:



Compounds of formula (I), , depicted in claim

1.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21, 22, 26 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claims are indefinite because they are in table form. Claims must stand alone to define the invention. Ex parte Fressola, 27 USPQ 2d 1608. This rejection can be overcome by inserting the structures claimed or by claiming the names of the compounds like in Claims 20, 23-25 and 27.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Finar, et al., Journal of the Chemical Society, Section B: Physical Organic, Vol. 2, pages 211-214, 1968, and Finar, I.L., Journal of the Chemical Society, Section B: Physical Organic, Vol. 7, pages 725-732, 1968).

Applicants claims of biphenyl substituted pyrazole compounds relate to compounds of Formula (I) in claim 1. Finar discloses biphenyl substituted pyrazole compounds that anticipate the instantly claimed genus wherein: **R1-R8** are hydrogen, which reads on the instant claims. (See Finar reference abstracts and CAS RN 19005-55-1, 1-[1,1'-biphenyl]-3-yl-1H-pyrazole.

Obviousness Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

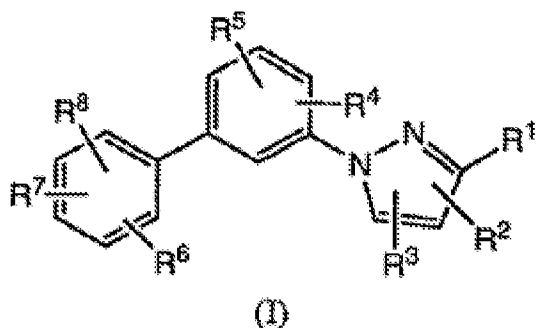
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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

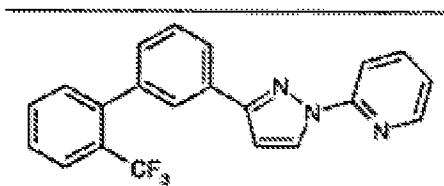
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 20-28 and 30-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of co-pending application no. 10/551,709 ('709 App). This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Applicants instant elected invention teaches the compound of formula (I),

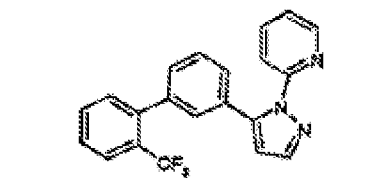


, depicted in claim 1, wherein the following preferred



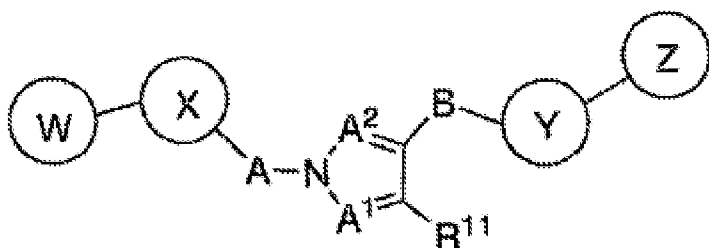
species can be found in claim 24,

and



These products are claimed as sodium channel blockers, useful in the treatment of a variety of disorders ranging from pain to disorders of the central nervous system in general.

'709 App claims compounds of formula (I),



, wherein the preferred species 2-(1-biphenyl-4-yl-1h-pyrazol-4-yl)-pyridine is found (See Claim 16, page 69, compound 1.) (In addition, see Claim 16, pages 69-70, compounds 2-4, 10, 16, 20, 23 and 24.)

These products are claimed as sodium channel blockers, useful in the treatment of a variety of disorders ranging from pain to disorders of the central nervous system in general.

The difference between the '709 App and the instant claims is that the moieties off the core are different. They are positional isomers and bioisosteres of one another.

One skilled in the art would have found the claimed compound *prima facie* obvious because the instantly claimed compound and the compound in copending applications are of the same class of compounds and there is significant overlap in the generic claims. Although, there are bioisosteric substitutions and positional isomers, one of ordinary skill in the art would be able to make the instantly claimed compounds based on the teachings of the copending application and vice versa.

The substitutions in the instant application are obvious. It is well known that adjacent homologues and structural isomers are generally so structurally similar that “without more” such structural similarity could give rise to *prima facie* obviousness. In re Wilder, 563 F.2d 457, 195

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USPQ 426. Also, hydrogen and methyl are deemed obvious variants. In re Wood, 199 USPQ 137. Bioisosteric substitutions are well known in the art. For example fluorine v. hydrogen, CH₃ v. CF₃, etc... See Patani et al., Chem. Rev., 1996, 96, 3147-3176, especially page 3149.

The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (i.e. pharmacological use as sodium channel blockers).

In addition, MPEP 804 states:

The doctrine of double patenting seeks to prevent the unjustified extension of patent exclusivity beyond the term of a patent. The public policy behind this doctrine is that:

The public should . . . be able to act on the assumption that upon the expiration of the patent it will be free to use not only the invention claimed in the patent but also modifications or variants which would have been obvious to those of ordinary skill in the art at the time the invention was made, taking into account the skill in the art and prior art other than the invention claimed in the issued patent. In re Zickendraht, 319 F.2d 225, 232, 138 USPQ 22, 27 (CCPA 1963) (Rich, J., concurring).

Double patenting results when the right to exclude granted by a first patent is unjustly extended by the grant of a later issued patent or patents. In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982).

Further, MPEP 804 (II) states:

A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Obviousness-type double patenting requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly owned patent, or a non-commonly owned patent but subject to a joint research agreement as set forth in 35 U.S.C. 103(c)(2) and (3), when the issuance of a second patent would provide unjustified extension of the term of the right to exclude granted by a patent. See *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 58 USPQ2d 1869 (Fed. Cir. 2001); *Ex parte Davis*, 56 USPQ2d 1434, 1435-36 (Bd. Pat. App. & Inter. 2000).

In conclusion, one skilled in the art would have found the variations in the instant application obvious when faced with the prior filed copending application because both compounds are used for the same pharmacological use so one skilled in the art would expect similar properties and results. Also, this application is junior to the other two copending applications and there is no reason why the instantly filed claims could not have been filed at that time.

Claim Objections

Claims 1, 24, 27, 30 and 31 are objected to for containing elected and non-elected subject matter. The non-elected subject matter has been identified supra.

Claim 1 is objected to because the variable Ra is not legible. The text should be enlarged so that it will be legible upon reprinting.

Claims 20-28 are objected to because some of the structures are unclear. The structures should be enlarged so that it will be legible upon reprinting.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/REI-TSANG SHIAO /
Primary Examiner, Art Unit 1626

Susannah Chung, July 1, 2008